JUL 2 3 2004

K041842

3. **510(k) Summary:**

Sponsor:	Synthes (USA) 1690 Russell Road Paoli, PA 19301 (610) 647-9700
Contact:	Sheri L. Musgnung
Device Name:	Norian SRS® Fast Set Putty
Device Classification:	21 CFR 888.3045 – "Resorbable Calcium Salt Bone Void Filler Device"
Predicate Device:	Norian SRS Bone Void Filler, K011897 Norian CRS Fast Set Putty, K012589
Description of Device:	Norian SRS Fast Set Putty is a self-setting calcium phosphate cement characterized by a rapid in situ setting time. The Fast Set Putty components are supplied sterile in two separate containers. The putty is intraoperatively prepared by manually mixing the components within a cup using a spatula. Once complete, the putty can be shaped and contoured by hand.
Indications:	Norian SRS Fast Set Putty is indicated only for filling bony voids or gaps that are not intrinsic to the stability of the bony structure. The putty is to be gently packed into bony voids or gaps of the skeletal system including the extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SRS Fast Set Putty provides a bone void filler that resorbs and is replaced with bone during the healing process.
Material:	Calcium Phosphate
Substantial Equivalence:	Documentation is provided which demonstrates that the Norian SRS Fast Set Putty is substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2004

Ms. Sheri L. Musgnung
Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
Paoli, PA 19301

Re: K041842
Norian SRS Fast Set Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: July 7, 2004
Received: July 8, 2004

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

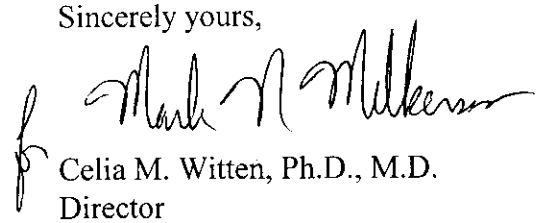
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2. Indications for Use

510(k) Number (if known): K041842

Device Name: Norian SRS® Fast Set Putty

Indications for Use: Norian SRS Fast Set Putty is indicated only for filling bony voids or gaps that are not intrinsic to the stability of the bony structure. The putty is to be gently packed into bony voids or gaps of the skeletal system including the extremities, spine, and pelvis. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. SRS Fast Set Putty provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041842